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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,591	08/19/2003	Takaaki Isshiki	0020-5166P	2938
2292 7590 03/16/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
OU, JING RUI				
ART UNIT		PAPER NUMBER		
3773				
NOTIFICATION DATE		DELIVERY MODE		
03/16/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/642,591

**Applicant(s)**

ISSHIKI ET AL.

**Examiner**

JING OU

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This action is responsive to the amendment filed on 12/01/2008. Claims 1 and 3-9 are pending. Claim 1 is independent. Claim 9 is newly added. Claim 2 is cancelled.

#### ***Specification***

2. The amendment filed on 12/01/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the embodiment shown in Figs. 3 and 13, the crossed wire member (31) comprises eight spirally-configured wires (311), i.e., four left-handed spiral wires (31 la) and four right-handed spiral wires (31 lb), which are fashioned into a spiral shape consisting of one turn. In the figures, all the right-handed spiral wires ('31 lb) are drawn by solid black lines, while the left-handed spiral wires (311 a) are drawn by broken lines cut off in the parts where the left- handed spiral wire ('31 l a) and right-handed spiral wire (31 lb) cross each other in Para.[0041] and Figures 3 5, and 13.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended recitation "a plurality of spirally-configured wires including right-handed spiral wires and left-handed spiral wires, one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft, while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally about the one of said either right-handed spiral wires or left handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other" in Claim 1 does not have sufficient support in the original disclosure and is considered as new matter.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116).

Khosravi discloses a sheath (the portion of sheath 52 which has the enlarged distal region of lumen 64 as described in col. 5, lines 19-22) being closed at the proximal end (by the narrow proximal region described in col. 5, lines 19-25), a flexible shaft (the combination of shaft 12 and member 54 which is attached thereto as indicated in col. 5, lines 32-35, and noting that shaft 12 is flexible in the embodiment described in col. 4, lines 13-16 due to the articulations therein), the flexible shaft being a wire member (Shaft 12 and attached member 54 together are a "wire" member since this member is very thin, as indicated in col. 5, lines 39-42, and elongated. The fact that the member has a passageway does not preclude the member from being a wire. For example, some guide wires have an elongated passageway through them for fluid delivery. Yet, they are wires.), thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and

mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). Khosravi fails to disclose the filter frame wires 24 comprising a plurality of spirally-configured wires including right-handed spiral wires and left-handed spiral wires, one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft, while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally about the one of said either right-handed spiral wires or left handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other. However, Brooks et al. teach that filter frame wires 56 comprising a plurality of spirally-configured wires (Fig. 4) including right-handed spiral wires and left-handed spiral wires, one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft, while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally about the one of said either right-handed spiral wires or left handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other (Fig. 4 and col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. As to claim 4, Khosravi fails to disclose a hemostatic valve and a tubular member to hold it. However, it is old and well known to use hemostatic valves and tubular members to hold the valves in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve and tubular member in the

Khosravi device so that it too would have this advantage. The proximal portion of shaft 12 of Khosravi protrudes from the sheath 52 when the shaft 12 is inserted therein as described in col. 5, lines 51-56. As to claim 7, Khosravi fails to disclose the slide ring assembly as comprising an inner ring and an outer ring with the wires sandwiched therebetween. However, it is old and well known in this art to secure wires between inner and outer rings in order to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Khosravi device so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Rosenbluth (WO 99/56801).

As to claim 5, Khosravi fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side hole 310 and second lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would

have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Boylan et al (US Pat. No.: 6,602,272).

As to claim 9, Khosravi in view of Brooks et al discloses all the limitations of the claim as taught above and further discloses that the filter is a funnel-shaped member including a constricting part and a constricted part extending from the smaller end of the constricting part, said constricting part being provided with plural pores. Khosravi in view of Brooks et al does not appear to disclose a cylindrical part. However, Boylan et al teaches a filter comprising a cylindrical part. The motivation/suggestion for doing so would have been served as a superstructure to which the filter and the struts of the strut assembly can be adhesively or otherwise affixed (Col. 5, lines 51-53). In addition, the cylindrical part provides better attachment of the filter to the blood vessel since more surface area of the filter contacts the blood vessel wall. Therefore, it would have been obvious to combine Boylan et al with Khosravi and Brooks et al to obtain the claimed invention as specified in the instant claim.

### ***Response to Arguments***

11. Applicant's arguments filed 12/01/2008 have been fully considered but they are not persuasive. The allegation on page 16 of the remarks that the filter assembly of Brooks et al differs in function and construction of the present invention since the filter assembly basket 58 is fixed to the guide wire 64 at its proximal end 66 and distal end 68



is incorrect. Though the filter assembly basket 58 of Brooks et al may be fixed to the guide wire 64 at its proximal end 66 and distal end 68, Khosravi teaches thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). The combination of the filter assembly of Khosravi and the filter assembly of Brooks et al has the same function and construction of the present claimed invention. The device of Khosravi is modified to have the filter frame wires including right-handed spiral wires and left-handed spiral wires, one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft, while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally about the one of said either right-handed spiral wires or left handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other as taught by Brooks et al (Fig. 4 and col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. Therefore, it would have been obvious to combine Brooks et al with Khosravi to obtain the invention as specified in the instant claims.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

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